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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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<div>140 7590 02/07/2008</div> <div>LADAS & PARRY LLP</div> <div>26 WEST 61ST STREET</div> <div>NEW YORK, NY 10023</div>				
<div>EXAMINER</div> <div>WESTERBERG, NISSA M</div>				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,321	Applicant(s) MARTINEZ ET AL.	
	Examiner Nissa M. Westerberg	Art Unit 4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 25 is/are pending in the application.
- 4a) Of the above claim(s) 7-14 and 21-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 6 and 15 - 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/02/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group III, sodium channels as the location of action and carbamazepine as the blocking agent in the reply filed on December 14, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

Claims 1 – 25 are pending. Claims 7 – 14 and 21 – 25 are withdrawn as not being drawn to the elected invention. Claims 1 – 6 and 15 – 20 are currently under examination.

Claim Rejections - 35 USC § 112 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 – 6 and 15 – 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims relate to agents that block the electrical activity of the damaged nerve endings of the neuroma. While examples of compounds that possess the ability to prevent or reduce discharges of nerve impulses in nueromas are provided, Applicant has not demonstrated that at the time of the application that they were in possession of the generic concept. This is a group of compounds defined by their function. The examples of chemical compounds provided may not be representative of the overall genus of agents that block electrical activity.

Claim Rejections - 35 USC § 112 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 15 – 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The word "including" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 – 4 and 15 – 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Shahinian, Jr. (US Patent 5,610,184).

Shahinian, Jr. discloses the use of proparacaine in a patient diagnosed with dry eye as well as post-operative PRK (photorefractive keratectomy) patients (Table 3, col 21, patients C15 and C18 – 24). Proparacaine is a local anesthetic (col 2, ln 18) that acts by blocking sodium channels, as evidenced by the Drug Bank Card for proparacaine (accessed 1/31/08, p 4 'pharmacology' and 'method of action' sections). The anesthetic is applied directly to the eye (col 2, ln 13 – 17). These pharmaceutical compositions can contain pharmaceutically acceptable excipients, additives and preservatives (col 3, ln 30 – 37).

The recitation of the cause of the dryness of the human eye (photorefractive surgery) has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535

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F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Therefore, the claim requires treating the dryness of the surface of the eye which comprises administering a blocking agent. Patients suffering from dry eye are suffering from dryness of the surface of the human and are treated with a local anesthetic blocking agent proparacaine in Shahinian, Jr. Shahinian, Jr. also discloses the treatment of patients with proparacaine after photorefractive surgery. Therefore, the claims of the instant application are anticipated by Shahinian, Jr.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1 – 6 and 15 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahinian, Jr. (US Patent '184) in view of Berger et al. (US Patent 5,688,830).

As discussed above, Shahinian, Jr. discloses the use of local anesthetics, such as the sodium-channel blocker proparacaine, in an ophthalmic composition with pharmaceutically acceptable excipients, additives and preservatives. Another compound disclosed as a local anesthetic is lidocaine (col 1, ln 26 – 31). These compositions of local anesthetics are administered to patients suffering from dry eye or those patients that have undergone PRK surgery.

Shahinian, Jr. does not disclose carbamazepine as a drug that is useful in these ophthalmic compositions.

Berger et al. discloses that sodium channel blocking agents are particularly useful as local anesthetics and in the treatment of pain. Examples of well-known sodium-channel blockers include lidocaine and carbamazepine (col 1, ln 41 – 46).

Proparacaine and carbamazepine are both drugs that block the activity of sodium-channels in neurons. It would have been obvious to one of ordinary skill in the art to replace the local anesthetic proparacaine in the ophthalmic composition with carbamazepine as these drugs are functional equivalents. As such, a person of ordinary skill in the art at the time of the instant invention would have had a reasonable expectation of success. The compositions of sodium-channel blocking agents have been used in the treatment of patients with dry eye as well as those patients who have undergone PRK so it would have been obvious to one of ordinary skill to use such a composition for the treatment of dryness of the eye and in patients who have undergone photorefractive surgery. Thus, the combined teachings of Shahinian Jr. and Berger et al. renders the claims of the instant application obvious to one of ordinary skill in the art at the time of the instant invention.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1 – 4 and 15 – 18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 51 and 52 of U.S. Patent No. 7,183,430 in view of Shahinian Jr. (US Pat '184).

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US '430 claims the use of various chemical compounds to attenuate the nervous activity of neurons involved in pain sensations that can be achieved by inhibition of ion channels that lead to the pain sensation (claim 52, col 36, ln 1 – 6). These compounds are inhibitors of the vanilloid receptor (col 2, ln 34 – 39), which is a cation channel that is permeable to calcium, sodium and potassium (p 9, col 1, paragraph 1 of Grant et al., J Pharmacol Exp Ther, 300(1): 9 – 17, 2002). Therefore, the compounds of US'430 are agents that block the electrical activity of nerves by exerting their actions on cation channels.

As discussed above, Shahihian Jr. discloses the use of local anesthetics such as proparecine and lidocaine, which block sodium-channel activity, in ophthalmic preparations with excipients that are administered to patients suffering from dry eye and patients who have undergone PRK. US '430 discloses compounds that are functionally equivalent to those taught in Shahihian Jr. as these compounds all block the action of cation channels in nerves. It would have been obvious to one of ordinary skill in the art at the time of the instant to replace the sodium channel proparacaine or lidocaine with the functional equivalent channel blockers taught in US '430. The resulting invention would encompass the administration of agents that block the electrical activity of a nerve cell to a subject suffering from dry eye or having undergone PRK surgery. That invention falls within the scope of claims 1 – 4 and 15 – 18 of the instant application.


Conclusion

Claims 1 – 6 and 15 – 20 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 7:30 a.m. - 5 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NMW


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